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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,926

11/18/2003

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AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER

SHEN, BIN

ART UNIT

PAPER NUMBER

1657

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,926

Applicant(s)

KNOX ET AL.

Examiner

Bin Shen

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-18,22-45 and 48-78 is/are pending in the application.
- 4a) Of the above claim(s) 17, 22,23,25-26,29,41-43, 45, 48-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-16,18,24,27,28,30,31 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

The IDS received 5/18/2004, the preliminary amendment received 4/5/2004 have been entered.

Election

Applicant's election with traverse of Group I, claims 1, 3-8, 22-31, 41-44, in the reply filed on 10/26/2006 is acknowledged. The traversal is on the ground(s) that the Groups share corresponding special technical feature. This is not found persuasive because PCT Rule 13.2 does not apply to the present application which is filed as a continuation of a PCT. Reasons for restriction/election based on distinctness and search burden are stated in previous office action. There is also search burden on non-patent literature, thus restriction/election is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17, 22-23, 25-26, 29, 41-43 are considered nonelected because they drawn to nonelected species and thus are withdrawn from further consideration.

Claims 1, 3-16, 18, 24, 27-28, 30-31, 44 are presented for examination on the merits.

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16, 18, 24, 27, 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the methods do not recite clear and positive steps. For example, there is no step a, step b, etc. In claim 1, "detecting" on line 2 is confusing since it is not clear what method (antibody detection, etc.) is used to detect the organism. In claims 1, 24, 27, 44 "capable of" does not state what actually occurs.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 8-13, 15, 18, 24, 28, 30, 31, 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanakas et al. (Fertility and Sterility 1999;71(3):523-527).

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Kanakas teaches a method for detecting the presence of a reproductive function-modulating organism, comprising detecting an organism which adhering to sperm and which correlates with an adverse assisted reproductive technology (ART) outcome (abstract), wherein the correlation is made if the organism remaining adherent to sperm after washing a sample comprising organism-positive sperm to permit one of removal and separation of non-sperm substances from the sample (bottom of left column of page 524-right column, line 11) wherein the washing is carried out using wash conditions that protect one or more viability properties of the sperm (bottom of left column of page 524), wherein the organism is *Ureaplasma urealyticum* from the genus *Mycoplasma* (page 524, left column, 5th full paragraph), wherein the adverse ART outcome is reduced fertilization rate (abstract-results & conclusions) and the ART is in vitro fertilization (page 524, left column, 1st full paragraph), wherein the biological sample is semen and spermatozoan (page 524, left column, 5th full paragraph, right column, 1st full paragraph).

Therefore, the cited reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

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art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-16, 18, 24, 27-28, 30-31, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kanakas et al. and Ng et al. (Human Reproduction 1992;7(2):261-266).

Kanakas et al. teaches what is above.

Kanakas does not teach the washing is carried out using a sperm swim-up technique and gradient centrifugation, diagnosing a risk of an adverse ART outcome.

Ng et al. teach a method of gradient centrifugation and a sperm swim-up technique for preparing spermatozoa from semen samples (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Kanakas to diagnose a risk of an adverse ART, and to modify the method of Kanakas et al. by using gradient centrifugation and sperm swim-up technique for preparing spermatozoa from semen because Ng teaches sequential gradient centrifugation and swim-up preparation improves yields of high quality spermatozoa from some abnormal semen samples and therefore has potential for improving fertilization rates (end of abstract). One would have been motivated to make the modification because Kanakas teaches a high incidence of *U. urealyticum* infection in asymptomatic men undergoing IVF (page 526, right column, 5th full paragraph, lines 2-3), suggesting for diagnostic use of the method by determine whether the outcome of IVF is associated with the presence of bacteria (page 523, left column, 2nd paragraph), and would reasonably have expected success in view of Ng's teaching that

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gradient centrifugation and sperm swim-up preparation of abnormal semen samples improve fertilization rate (end of abstract). The choices of, if the washed sperm sample comprise at least 0.01% of the total number of organism present in the sperm sample before washing to make the correlation of the presence of an organism with an adverse ART outcome, the washing is carried out using wash conditions that permit continuation of adherence of *Ureaplasma parvum* serotype 6 to the sperm but that do not permit continuation of adherence of *U. parvum* serotype 1 to the sperm, the organism is subtype of *Ureaplasma parvum* serotype 6 selected from *Mycoplasma hominis*, are deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

5. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does

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submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should

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be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.



RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200

B Shen

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